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Display Date 12-1-00
Publication Date 12-4-00
Certifier SKeene

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1639]

SangStat Medical Corp.; Withdrawal of Approval of an Abbreviated New Drug Application; Cyclosporine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of an abbreviated new drug application (ANDA) held by SangStat Medical Corp., 6300 Dumbarton Circle, Fremont, CA 94555 (Sangstat). The ANDA is for SangCya Oral Solution (Cyclosporine Oral Solution, USP) Modified, which was the subject of a class II recall announced on July 10, 2000. SangStat has agreed in writing to permit FDA to withdraw approval of the application and has waived its opportunity for a hearing.

EFFECTIVE DATE: [Insert date 30 days after date of publication in the FEDERAL REGISTER.]

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: On July 10, 2000, SangCya Oral Solution (Cyclosporine Oral Solution, USP) Modified, 100 milligrams per milliliter, was the subject of a class II recall under 21 CFR part 7 (Ref. 1). The recall of the drug product, marketed under ANDA 64-195, arose from data recently submitted by SangStat to the agency regarding the bioavailability of the product in healthy subjects when administered with apple juice. Following the recall, SangStat notified the agency in writing on July 21, 2000, that the company had decided to permanently withdraw the product from the market. On August 4, 2000, SangStat requested in writing that the agency withdraw approval of ANDA 64-195. Subsequently, SangStat provided the agency with a full and complete waiver of the company's right to a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) to allow the agency to complete the withdrawal of approval under 21 CFR 314.150(d).

Therefore, under section 505(e) of the act and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of ANDA 64-195, and all amendments and supplements thereto, is hereby withdrawn, effective [insert date 30 days after date of publication in the FEDERAL REGISTER]. The effective date of the withdrawal of approval is intended to allow patients the opportunity to complete their transition to another cyclosporine drug product (see Ref. 1). Thereafter, distribution of the

product in interstate commerce without an approved application is illegal and subject to regulatory action. Also, on the basis of the circumstances described above that led to the recall of the product and its subsequent removal from the market, the agency will remove the product from the agency's list of drug products with effective approvals, published under the title "Approved Drug Products with Therapeutic Equivalence Evaluations." This document serves as notice of the removal of the product covered by ANDA 64-195, SangCya Oral Solution, from the list of approved drug products.

Reference

The following reference has been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The document may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. The document is available on the Internet at http:www//fda.gov/bbs/topics/ANSWERS/ANS01025.html.

1. FDA Talk Paper dated July 10, 2000.

Dated: 11/21/00
November 21, 2000

Janet Woodcock,
Director,
Center for Drug Evaluation and Research.